U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT M&O-ARP-00-02

OF THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT SYSTEM
MANAGEMENT AND OPERATING CONTRACTOR

AT

LAS VEGAS, NEVADA

NOVEMBER 15–19, 1999

Prepared by: _____ Date: _____
Donald J. Harris
Audit Team Leader
Office of Quality Assurance

Approved by: _____ Date: _____
Robert W. Clark, Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

This performance-based Quality Assurance (QA) Audit was conducted on the processes and activities related to the Biosphere Process Model Report (PMR) at the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) offices in Las Vegas, Nevada, November 15–19, 1999. The purpose of the audit was to evaluate the effectiveness of the Analysis and Model Report (AMR) process and the quality of the three AMR products of the 15 AMRs that feed the Biosphere PMR.

The audit team determined that the CRWMS M&O has effectively implemented the critical process steps relative to Biosphere activities evaluated with the following exceptions: deficiencies were identified in the areas of Technical Product Development Planning (TPDP), Documenting and Verifying Traceability for the Requirements Traceability Network (RTN), Analysis and Models, Technical Product Input, and Control of the Electronic Management of Data (refer to Section 5.0 for specific details). Based upon the review of in-process documentation, interviews of personnel, and examination of the procedure processes, the audit team determined that the Biosphere activities being conducted at the time of the audit meet Office of Civilian Radioactive Waste Management (OCRWM) QA program requirements. It should be noted that two of the AMRs were approved, and one was still in the technical review process.

The audit team identified eight deficient conditions that were addressed in two Deficiency Reports (DR) and four Deficiency Identification and Referral (DIR) documents, which were added to the extent of condition of a previously issued open deficiency documents. DR LVMO-00-D-021, which addresses that the TPDP for the AMRs, was developed and approved without considering the control of the electronic management of data or satisfying all the requirements of AP-2.13Q, Revision 0, ICN 1, "Technical Product Development Planning," Attachment 3. DR LVMO-00-D-023 addresses the RTN 007 report for the CRWMS M&O, that reflects procedures superseded by OCRWM Administrative Procedures (AP) that are actually being implemented. DIR issued to LVMO-99-C-001 addresses AP-3.10Q, Revision 1, ICN 1, "Analysis and Models" requirements that were not satisfied, e.g., checker's comments resolved verbally, analysis did not fulfill the objective of the TPDP, and the Technical Judgment of the originator was not justified. DIR issued to LVMO-98-C-002 addressed AP-3.15Q, Revision 1, "Managing Technical Product Inputs," where an input request was not processed in accordance with AP-3.14Q, Revision 0,"Transmittal of Input." DIR issued to LVMO-98-C-010 addresses AP-3.10Q, where the AMR data combined with GENII-S software to perform a pathway analysis becomes a model and model validation was not addressed in the AMRs or the TPDP. DIR issued to LVMO-98-D-055 addresses the fact that YAP SV.1Q, Revision 0, ICN 1, "Control of the Electronic Management of Data" checklist was not generated to determine if QARD, Supplement V, "Control of the Electronic Management of Data" applied.

There were two deficient conditions identified that only required remedial action that were Corrected During the Audit (CDA). Details of the CDA conditions are documented in Section 5.5.3 of the report. Additionally, there were nine recommendations resulting from the audit, as documented in Section 6.0 of the report.

2.0 SCOPE

The audit was conducted to evaluate the effectiveness of the AMR process for the development of the Biosphere PMR. The audit team evaluated the documented activities that constitute scientific and performance assessment analyses and models pertaining to the Biosphere. The related AMRs and supporting documents were examined to determine the effectiveness of the analysis in providing evidence to support the Biosphere PMR.

The Biosphere AMRs will support the Total System Performance Assessment (TSPA) on the subject and serve as an important reference to the License Application. The following process and products were examined as part of this audit:

- Draft Work Package Planning Summary Biosphere-Related AMRs and PMR, Revision 00A, Document Identifier (DI) Number WPP-MGR-MD-000047
- Draft Work Package Planning Summary, Biosphere Abstraction and Testing, Revision 00, DI Number WPP-NBS-MD-000001
- Development Plan, “Transfer Coefficient Analysis,” Revision 1, DI Number TDP-MGR-MD-000006
- Development Plan, “Dose Conversion Factor Analysis,” Revision 1, DI Number TDP-MGR-MD-000007
- Development Plan, “Disruptive Event Biosphere Dose Conversion Factor Analysis,” Revision 1, DI Number TDP-MGR-MD-000008
- ANL-MGR-MD-000002, Revision 00, Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods (AMR-B0045)
- Draft, ANL-MGR-MD-000003, Revision 00B, Disruptive Event Biosphere Dose Conversion Factor Analysis. (AMR-B0055)
- ANL-MGR-MD-000008, Revision 00, Transfer Coefficient Analysis (AMR-B0040)
- The Analysis and Model process from Planning through submittal of data and models to the Technical Data Management System (TDMS)

The audit team conducted personnel interviews and examined documentation in accordance with the approved audit plan to evaluate the adequacy and effectiveness of the critical process steps for the development of the AMRs that support the Biosphere PMR.

2.1 Process Steps/Products/Documentation

The performance-based evaluation of process effectiveness was based upon the following:

1. Satisfactory completion of the critical process steps
2. Documentation that substantiates quality and traceability of data
3. Performance of trained and qualified personnel
4. Implementation of applicable QA program elements

The following critical process steps were considered during the evaluation of the AMR process:

- Planning
- Resources
- Methodology
  - Procedures
  - Scoping
  - Data Acquisition
  - Data Qualification
  - Analyses, Modeling
- Adequacy and Accuracy
  - Checks/Reviews
- Deliverables
  - Record Submittals

2.2 The audit included a technical evaluation of the adequacy and effectiveness of the AMR/PMR process. Details of the technical evaluation are documented in Section 5.4 of this report.

3.0 AUDIT TEAM MEMBERS/OBSERVERS

Donald J. Harris, Audit Team Leader, Office of Quality Assurance (OQA)
Kenneth T. McFall, Auditor, OQA
Larry G. Abernathy, Auditor, OQA
F. Harvey Dove, Technical Specialist, OQA
Brenda R. Bowlby, Technical Specialist, Management Technical Support
Chao-Hsiung Tung, CRWMS M&O, Technical Specialist

There were four observers present during the audit:

Larry Campbell, U. S. Nuclear Regulatory Commission (NRC), White Flint, Maryland
Kien Chang, NRC Headquarters, White Flint, Maryland
Bob Brient, NRC, Center for Nuclear Waste, Regulatory Analysis, San Antonio, Texas
Pat LaPlante, NRC, Center for Nuclear Waste, Regulatory Analysis, San Antonio, Texas

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was conducted at the CRWMS M&O Offices, Las Vegas, Nevada, on November 15, 1999. Daily debriefings were held to apprise the CRWMS M&O management and staff of the progress of the audit and of any potential conditions adverse to quality. A post-audit meeting was conducted at the CRWMS M&O Offices, Las Vegas, Nevada, on November 19, 1999.

Personnel contacted during the audit, including those that attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that critical process steps applicable to the AMR/PMR process were effectively implemented; however, eight deficient conditions were identified relating to procedure implementation, which resulted in the issuance of two new DRs, four DIRs referred to existing DRs/Corrective Actions Reports (CAR) and two CDAs. Details of these deficient conditions adverse to quality are presented in Section 5.5 of this report. In addition, nine recommendations are provided in Section 6.0 of this report.

During the audit, corrective action was evaluated with relation to the significant deficiencies documented in existing CAR that could impact the Biosphere AMR process. The following is a status of the CARs as a result of the evaluation conducted during the audit:

CAR LVMO-99-C-001

Based on reviews during the Biosphere audit, this CAR will remain open.

The assessment of procedure AP-3.10Q, Revision 1, ICN 1, "Analysis and Models," resulted in unsatisfactory procedure implementation problems in the AMR development and checking process. See DIR to CAR LVMO-99-C-001 in Section 5.5.1 of this report.

The verification will continue through the OQA Phase 3 verification activities and review of PMR audits.

CAR LVMO-98-C-002

Based upon the reviews during the Biosphere audit, this CAR will remain open.

AP-3.15Q, Revision 0, ICN 1, "Managing Technical Product Inputs," a Technical Product Input Request was not processed for inputs from other than a controlled source, in accordance with AP-3.14Q, Revision 0, "Transmittal of Input" for confirmation that the technical product input is suitable for intended use and placed in a controlled source, for ANL-MGR-MD-000008, Transfer Coefficient Analysis. See DIR to CAR LVMO-98-C-002 in Section 5.5.1 of this report.

The verification will continue through the OQA Phase 3 verification activities and review of PMR audits.

CAR LVMO-98-C-006

Based upon the reviews during the Biosphere Audit, it was concluded the GENII-S, VI.4.8.5 software was qualified in June of 1998, in accordance with QAP SI-3, Revision 3, "Software Configuration Management," reverified by checklist in April 1999 in accordance with QAP SI-0, Revision 4, "Computer Software Qualification," and again by checklist for reconfirmation for CAR LVMO-98-C-006 in July 1999. No deficient conditions were noted.

The verification will continue through the OQA Phase 3 verification activities and review of PMR audits.

CAR LVMO-98-C-010

Based on the reviews during the Biosphere audit, this CAR will remain open.

Concerns in the area of model validation were raised during the audit. A DIR to CAR LVMO-98-C-010 was generated, which documents that the audited AMRs were inaccurately designated as "Analyses" rather than "Models." Therefore, model validation was not addressed as required by AP-3.10Q, "Analyses and Models." See DIR to CAR LVMO-98-C-010 in Section 5.5.1 of this report.

The verification will continue through the OQA Phase 3 verification activities and review of PMR audits.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions taken as a result of the audit.

5.3 QA Program Activities

Attachment 2, "Summary Table of Audit Results," provides results for each critical process step evaluated. Attachment 3, "Summary Table of Audit Results for Procedure Compliance Evaluations," provides the results of procedure compliance evaluations. Details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA Record.

5.4 Technical Audit Activities

AMR ANL-MGR-MD-000002, Dose Conversion Factor Analysis: Evaluation of GENII-S Dose Assessment Methods.

This AMR was prepared to support the Biosphere PMR that summarizes Biosphere modeling efforts. The AMR was approved by the Responsible Manager on October 13, 1999. The audit team examined and reviewed the AMR report, pertinent records, supporting documents, and conducted interviews of the author and other key personnel. These individuals are associated with the CRWMS M&O Radiological and Environmental Programs Department and Environmental Sciences Department.

The principal procedure governing the preparation of AMRs is AP 3.10Q. The audit team examined the AMR report and used the information in the reports, along with the checklists, to structure the interviews of personnel. The AMR appears to be a good starting point for the technical product, though the AMR could be improved, based on the lack of clarity of the scope and several other weak links identified by the audit team.

1. The lack of upper tier flow down planning guidance had a negative effect on the quality of the product. The originator was assigned by the supervisor to prepare a TPDP for this AMR in the absence of any upper tier planning guidance (Work Package Planning Summary [WPPS]). As a result, the TPDP was prepared without a clearly defined scope (e.g., the applicable time span). A draft WPPS was presented to the audit team during the audit; however, the draft was incomplete for the assessment for its adequacy. It is recommended that the WPPS be completed prior to the commencement of the task in order to have a well-defined scope for the product. (Recommendation 9)

2. The audit team determined that the checking process could be improved in many aspects, such as formalizing the documentation of the comment and the comment resolution. Check copies of the AMR were examined and the checker was interviewed. The checking process was conducted with cooperation from the author. All comments and suggestions appeared to be resolved and incorporated satisfactorily; however, the checker's comments and originators comment resolution are color-coded without any other designation, when the comments are resolved verbally, there is no objective evidence of resolution. Once the marked-up analysis is submitted to records, especially when the handwriting is similar, it is difficult to determine that the comment was resolved because the record is in black and white, or the comment was resolved verbally. (Recommendation 5c) Also, the checking process should have recognized the deviation of the AMR from the TPDP. The AMR presents an argument for using GENII-S to calculate internal dose conversion factors and FGR-12 to calculate the external dose conversion factors and ensures that doses calculated by dose assessment component of GENII-S are consistent with doses calculated using similar methods currently accepted by the scientific and engineering community in the field of radiation protection. However, this AMR has not achieved the objective and fulfilled the scope defined in the TPDP and the tasks outlined in the TPDP were not fully accomplished. Specifically, the deviation includes (1) the AMR did not evaluate GENII-S dosimetric parameters for application to development of biosphere dose conversion factors for undisruptive performance and for disruptive events, (2) the AMR did not perform a scientific literature search to evaluate adequacy of the existing GENII-S parameters for the scenarios under consideration, (3) no methods were developed to incorporate appropriate parameters into the calculations. Though these deviations might not impact the technical correctness of the results, it should be noted that they may detract from the technical content of the document. (Recommendation 5e)

3. The AMR, while technically adequate, does not fully document the thought processes to allow readers to reach the same level of understanding on the subject as the author. The majority of decisions were based on technical judgment without presenting a "justification." Discussion with the author revealed that AP-3.10Q was not followed. (Recommendation 5d)

4. The principal computer software is GENII-S, which is a software containing a pathway analysis model and used to perform dose assessment calculations. Although GENII-S is qualified software, it is unclear as to what stage this "software" is being used to perform modeling. The audit team examined two background information documents in the form of e-mail messages: (1) "Models for Biosphere" from Kurt Raustenstrauch to Steve Bodnar (11/11/99), stating: "The Biosphere PMR and associated AMRs will be using only one model, titled "Biosphere;" and, (2) "Model Validation Step Needed

in Schedule," from Jeff Tapen to Glen Hanson (8/2/99), stating that the responsible management, although recognizing that GENII-S contains models, decided that no model validation will be performed. The lead supervisor was also interviewed at great length on this issue. It appears that the necessity for model validation was examined but rejected without justification by the responsible management. It is recommended that a model validation effort be conducted in order to enhance the confidence level of the Biosphere-related AMR results. (Recommendation 6)

AMR ANL-MGR-MD-000003, Revision 00B, Disruptive Event Biosphere Dose Conversion Factor Analysis

AMR ANL-MGR-MD-000003 REV 00B, was a work in process developed to support the Biosphere PMR. The audit team reviewed the AMR, task planning, AP-3.10Q process documentation, and conducted extensive interviews with the author. The members of the technical staff within the Environment, Safety and Regional Programs Office were cooperative and very knowledgeable of the biosphere exposure pathways and processes imbedded in the Biosphere Model developed using the GENII-S software. Results of the AMR were:

- The application of unqualified software, Crystal Ball and ASHPLUME v1.3, and corresponding use of analytical results were eliminated from the AMR by the author.
- Each of the AMR assumptions were discussed in detail during the audit with the rationale in support of all assumptions to be significantly strengthened in the final version of the AMR. (Recommendation 5d)
- Data obtained from an uncontrolled source were appropriately documented using an input transmittal form in accordance with AP-3.14Q, Revision 0, "Transmittal of Input."
- While the AMR was designated as an analysis, this report actually documented the use of GENII-S software to evaluate multiple exposure pathways following a hypothetical volcanic event scenario. This application of the GENII-S software established the AMR as a model instead of an analysis. The AMR did not mention model validation. (Recommendation 6)

The major process issue is when will the validation of the Biosphere Model, developed using the GENII-S software, be performed. Because the planning for the PMR was still in process, the validation of the Biosphere Model was not addressed. The AMRs were designated as analyses rather than models, and model validation was not addressed. Thus, the subject of model validation was not addressed at the AMR level with no plans to address model validation at the PMR level. The audit team further recommended that a separate AMR be scheduled to document validation of the composite Biosphere Model. (Recommendation 6)

Another related process issue is the proper identification of the technical product as a calculation, analysis, or model. There is no procedural guidance or criteria for making the decision. Some of the biosphere AMRs may have been completed as calculations in accordance with AP-3.12Q, Revision 0, "Calculations." This level of treatment and documentation may have been adequate for the intended use of the data developed in the AMR.

AMR ANL-MGR-MD-000008, Transfer Coefficient Analysis

The AMR was prepared to develop a defensible set of element-specific transfer coefficients for application in calculations of radionuclide-specific Biosphere Dose Conversion Factors (BDCF) for disruptive and nondisruptive events. Both reasonable and bounding cases were considered.

The audit team examined and reviewed the AMR, its planning document and pertinent supporting documentation, and conducted interviews of the document originator and other key personnel. Based on the audit results, the audit team concluded the scope was well defined, the methods used were appropriate, the technical content sound, and the data selection process reasonable.

Both the planning document and the AMR adequately explain the description and function of transfer coefficients and the environmental parameters selected. The method described in these documents and employed in this study is an evaluation of scientific and technical literature. The magnitude of variation expected from the literature search was addressed by selecting reputable sources and implementing a parameter selection process based on the frequency in which sources reported the same values as well as placing additional importance on those values reported for more recent studies.

Although the Transfer Coefficient AMR appears to be a sound technical document, one recommendation for improvement is noted. While reviewing the initial, backcheck, and final check copies of the AMR, it was apparent that most comments identified by both checkers were incorporated into the final document. Those comments not incorporated by the document originator were reportedly resolved informally with the checkers. The integrity of the final document resulting from this informal comment resolution process could be challenged in the future by relying solely on the longevity and memory of the personnel involved with this AMR. Therefore, it is recommended that comment resolution be formally documented between the checker and the originator during the checking process, and that AP-3.10Q be revised accordingly. (Recommendation 5c)

5.5 Summary of Conditions Adverse to Quality

The audit team identified eight deficiencies during the audit, which resulted in the issuance of two DRs. Four are addressed on DIR forms to existing CARs/DRs and two were CDA. These deficiencies are discussed in detail in Sections 5.5.1, 5.5.2, and 5.5.3.

5.5.1 Corrective Action Requests (CAR)

No new CARs were issued; however, three DIRs were issued to existing CARs as follows:

DIR to LVMO-99-C-00l

AP-3.10Q, Revision 1, ICN 1, "Analysis and Models"

The checking process failed to identify that the ANL-MGR-MD-000002, did not fulfill the objective of the TDM-MGR-MD-000007 Dose Conversion Factor, planning document.

The technical judgment of the originator on the decisions made were not justified and the checker failed to address the lack of justifications in ANL-MGR-MD-000002, Dose Conversion Factor.

DIR to LVMO-98-C-002

AP-3.15, Revision 0, ICN 1, "Managing Technical Product Inputs"

An Input Request was not processed in accordance with AP-3.14Q for Technical Product Inputs (other than accepted data) for ANL-MGR-MD-000008, Transfer Coefficient Analysis.

DIR to LVMO-98-C-010

AP-3.10Q, Revision 1, ICN 1, "Analysis and Models"

The Analysis ANL-MGR-MD-000002, ANL-MGR-MD-000003, and ANL-MGR-MD-000008, were performed using qualified GENII-S Software; however, when it is combined with data to perform a pathway analysis, it becomes a model, and therefore needs to be validated. (The AMRs were identified as "Analyses" rather than "Models").

5.5.2 Deficiency Reports (DR)

LVMO-00-D-021

AP-2.13Q, Revision 0, ICN 1, "Technical Product Development Planning"

Contrary to applicable requirements, YAP-SV.1Q, Revision 0, ICN 1, "Control of the Electronic Management of Data," was not considered as an applicable procedure in the Development Plans (TDP-MGR-MD-000006, TDP-MGR-MD-000007, or TDP-MGR-MD-000008).

YAP-SV.1Q applies when electronic media are relied upon for the control and access to data that are acquired, developed, or used during any phase of design analysis, process control, or Scientific Investigation process.

Contrary to applicable requirements, the Attachment 3 requirements under "Responsibilities" (first paragraph) and the "Description of Technical Products" (first paragraph) were not addressed in the following Technical Development Plans: TDP-MGR-MD-000006, TDP-MGR-MD-000007, and TDP-MGR-MD-000008.

LVMO-00-D-023

DOE/RW-0333P, Revision 8, "Quality Assurance Requirements and Description" (QARD)

Contrary to the applicable requirements, the RTN 007 report for the CRWMS M&O, dated November 10, 1999, indicates QAP-SIII.1, Revision 3, "Scientific Investigation Control," as the document that satisfies the QARD, subsection 2.2.5, "Planning Work," and QARD, Supplement III, subsection III.2.1, "Planning Scientific Investigations." Actually, AP-2.15, "Work Package Planning Summaries," and AP-2.13, "Technical Product Development Planning," effective June 30, 1999, are being implemented by the CRWMS M&O.

NOTE: DR YMSCO-98-D-125 identified similar matrix inaccuracies, which were limited to YMSCO/OQA for corrective action. This DR is limited to the CRWMS M&O for corrective action.

DIR to LVMO-98-D-055

YAP-SV.1Q, Revision 0, ICN 1, "Control of the Electronic Management of Data"

YAP-SV.1Q, Attachment 3, Process Control Evaluation for Supplement V Checklist, was not generated to determine if Supplement V applied for the following Technical Document Plans: TDP-MGR-MD-000006, TDP-MGR-MD-000007, and TDP-MGR-MD-000008.

5.5.3 Deficiencies Corrected During the Audit (CDA)

AP-3.15Q, Revision 0, "Managing Technical Inputs"

1. Paragraph 5.2.1 g) If technical product inputs are previously tracked as TBV/TBD, document the TBV/TBD tracking number, description and priority on the Document Input Reference Sheet (DIRS).
   Actual: The DIRS for the Disruptive Event BDCFs Analysis, the input code (GENII-S.1.485, Environmental Radiation Documenting Software System) was dropped from the DIRS. This was verified as CDA by revising the DIRS to include the input code.

2. Paragraph 5.2.1 i) If unqualified/untracked (i.e., initial use – not being tracked under a previous TBV/TBD tracking number) technical product input does not require a TBV/TBD tracking number per the TBV/TBD Logic Flow Diagram, document the justification in the technical product being developed.
   Actual: The Transfer Coefficient Analysis justification was missing from the text of the document. Justification was incorporated in the Technical Product during the audit.

6.0 RECOMMENDATIONS

1. Revise AP-2.13Q, Paragraph 5.2. e)4) "Note" remove the word "recommended." The Development Plan checklist, Item 4, requires "Identify and/or create implementing documents (Procedures) required to perform the work." The word "recommended" is in conflict with the requirement.

2. Revise the TDP MGR-MD-000007 and ANL-MGR-MD-000002, Dose Conversion Factor, to clearly define the Scope Applicable Time Span.

3. Revise AP-2.14Q, Revision 0, "Review of Technical Products," to discuss the use of the Analysis Model Checklist, that is in the Automated Forms System (AFS) form finder, as guidance for the review, and retain the completed form as a record of the review.

4. Revise AP-2.14Q, to remove the alternate method of performing technical reviews contained in Paragraph 5.2 d) of marking up the copies. The OCRWM Comment Sheet (AP 5.1Q.5) should be used to document and resolve comments for a defensible project position.

5. Revise AP-3.10Q, to address the following:

   a) Provide specific criteria for what constitutes an analysis or model or an analysis/model in the procedure, then provide guidance for the processing of each category. (Confusion existed during this audit, by marking "Analysis/Model cover sheet as an "Analysis." Consequently, all the model/validation requirements in the procedure were not implemented).

   b) Discuss the use of the Analysis Model Checklist, that is in the AFS form finder, as guidance for the checker's review, and retain the completed form as a record of the review.

   c) Require the Checking Comment Resolution process to require the comment resolution to be documented. The checker's comments and originators comment resolution are color-coded without any other designation, when the comments are resolved verbally, there is no objective evidence of resolution. Once the Markup Analysis is submitted to records, especially when the handwriting is similar, it is difficult to determine that the comment was resolved because the record is in black and white.

   d) Revise Paragraph 5.5.3 6) to require justification based on technical judgment (the thought process, while technically adequate, was not fully documented. Consequently, the readers of the analysis could not reach the same understanding on the subject).

   e) Include a requirement for the originator and checker to review the analysis for compliance to the WPPS and the TPDP.

6. A separate AMR that is dedicated solely to validation of the Biosphere GENII-S composite model should be developed.

7. Generate management guidance or criteria to determine when it is an Analysis, Model, Analysis/Model or calculation. It appears that some of the Biosphere AMRs could have been completed as calculations in accordance with AP-3.12Q calculations.

8. The Control of the Electronic Management of Data in the Biosphere WPPS and the TPDP should be addressed.

9. The AP-2.15Q WPPS should be generated and approved prior to the initiation of the lower tier AP-2.13Q, “Technical Products Development Planning,” in order to have a well-defined Scope of Work in the planning documents.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Critical Process Steps Evaluated
Attachment 3: Summary of Audit Results for Procedure Compliance

ATTACHMENT 1

PERSONNEL CONTACTED

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Andrews, Robert	M&O/Performance Assessment Operations Manager	X		
Beesley, John	M&O, Technical Checker	X		X
Bhattacharyya, K. K.	M&O/Engineered Barrier System Operation, Manager			X
Blaylock, Jim	DOE/OQA Engineer	X		
Brient, Robert D.	USNRC, Observation Team Leader	X		X
Campbell, Larry L.	USNRC, Senior QA Engineer	X		
Carlisle, Greg	M&O Software Configuration Management		X	
Chang, Kien C.	USNRC, Observation Team Leader	X		X
Croft, Larry D.	M&O/Radiological and Environmental Programs Department, Manager	X	X	X
Dana, Steve	QATSS/OQA, Lead Quality Engineer	X		
Fray, Russ	M&O/SAIC, Support Operations Manager	X		X
Glasser, William	OQA/QATSS, Senior QA Specialist	X		
Greene, Hank	OQA/QATSS, Manager, Quality Systems			X
Green, Ron	M&O/Environmental Sciences Department Manager	X		X
Hammond, Phil	M&O/Repository Systems Operations, Manager, Process Improvement and Configuration Management			X
Hanson, Glen T.	M&O/Regulatory and Licensing Group, Manager			X
Harris, Mike	M&O/Environment, Safety, & Regional Programs, Office Manager			X
Hartstern, Robert	OQA/QATSS, Senior QA Specialist	X		
Hasson, Robert	OQA/QATSS, Verification Lead			X
Howard, Robert	M&O, Data and Code Project Manager	X		X
Kimble, Robert	BA&H/Supervisor, Regional Studies		X	X
Kunihiro, Dean	M&O, Executive Staff Director			X
La Plante, Patrick	NRC/CNWBA, Senior Scientist	X		
Lederle, Pat	M&O/Environmental Sciences Department, Scientist	X	X	X
Lentz, F. H.	QATSS/OQA Senior QA Specialist	X		X
Liu, Ning	M&O/Radiation Programs Department, Health Physicist	X		X
Lugo, Mike	M&O, Regulatory & Licensing Manager	X		
Murthy, Ram B.	DOE/OQA Lead			X

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Opelski, E. P.	OQA/QATSS, Verification Manager			X
Peppers, Donald	M&O Software Analyst		X	
Peters, John	M&O/Morrison Knudsen Engineers, Manager, Engineering Services	X		
Prince, J. K.	M&O, Senior Scientist	X		
Rautenstrauch, Kurt	M&O/Environmental Sciences Department, Supervisor,	X	X	X
Schmitt, John F.	M&O, Supervisor, Radiation Programs	X	X	X
Segrest, Alden	M&O, Department Manager			X
Smith, A. J.	M&O/Duke, Transport and Biosphere			X
Spangler, Elaine	M&O/SAIC, M&O Training		X	
Swanson, D. A.	M&O/SAIC, Senior Scientist			X
Tappen, Jeffrey J.	M&O, Principal Health Physicist	X	X	X
Thompson, Kathleen	M&O/SAIC, Records Specialist		X	
Wasiolek, Maryla	M&O, Health Physicist, Radiation and Environmental Programs Department	X	X	X
Wolverton, Ken W.	M&O/QA Liaison	X	X	X
Wu, Wesley	BA&H/Scientist, Radiation and Environmental Programs Department	X	X	X
Younker, Jean	M&O/MGR Deputy Technical	X	X	X
Zinkevich, Fred N.	M&O/Project Manager, QA Coordination			X

Legend:
BA&H – Booz, Allen & Hamilton, Inc.
M&O – Management and Operating Contractor
QA – Quality Assurance
OQA – Office of Quality Assurance
QATSS – Quality Assurance Technical Support Services
SAIC – Science Applications International Corporation
USNRC – U. S. Nuclear Regulatory Commission

ATTACHMENT 2

SUMMARY OF TABLE OF AUDIT RESULTS
CRITICAL PROCESS STEPS

Products	Critical Process Steps	Details Checklist	Deficiencies	Recommendations	Process Effectiveness	Product Adequacy	Overall
ANL-MGR-MD-000002 ANL-MGR-MD-000003 ANL-MGR-MD-000008	Planning	Pgs 1-15, 59, 60, 66-67	LVMO-00-D-021	1, 2, 8 & 9	SAT	SAT	SAT
	Resources	Pgs 16-29, 61	DIR/LVMO-98-D-055	NA	SAT	SAT	SAT
	Procedure	Pgs 30-39	LVMO-00-D-021	N/A	SAT	SAT	SAT
	Scoping	Pgs 40-51	N/A	N/A	SAT	SAT	SAT
	Data Acquisition	Pgs 52-59, 61-63, 73	DIR/LVMO-98-C-002	N/A	SAT	SAT	SAT
	Data Qualification	Pgs 63-65, 78-92	N/A	N/A	SAT	SAT	SAT
	Analysis	Pgs 68-72, 74-76, 93-98	N/A	7, 8	SAT	SAT	SAT
	Modeling	Pgs 61, 62	DIR/LVMO-98-C-010	5, 6, 7	UNSAT	UNSAT	UNSAT
	Checks	Pgs 65, 77, 99-105	DIR/LVMO-99-C-001	5	SAT	SAT	SAT
	Reviews	Pgs 105-116	DIR/LVMO-99-C-001	3, 4	SAT	SAT	SAT
	Records	Pgs 117-131	N/A	N/A	SAT	SAT	SAT

ATTACHMENT 3

PROCEDURE COMPLIANCE REQUEST

QARD Element	Implementing Document	Details Checklist	Deficiency Reports	CDA	Recommendations	Program Adequacy	Procedure Compliance	Overall
2.0	AP-2.1Q	Pgs 16-18	N/A	N/A	N/A	SAT	SAT	SAT
	AP-2.2Q	Pgs 19-21	N/A	N/A	N/A	SAT	SAT	SAT
	AP-2.13Q	Pgs 4-18	LVMO-00-D-021	N/A	1, 2, 8	SAT	SAT	SAT
	AP-2.14Q	Pgs 102-116	N/A	N/A	3, 4	SAT	SAT	SAT
	AP-2.15Q	Pg 1-6	N/A	N/A	9	SAT	SAT	SAT
3.0	AP-3.4Q	Pgs 34-36, 120-122	N/A	N/A	N/A	SAT	SAT	SAT
	AP-3.10Q	Pgs 93-101	DIR/LVMO-99-C-001 DIR/LVMO-98-C-010	N/A	5(a-e)-7	Marginal	UNSAT	UNSAT
	AP-3.15Q	Pgs 40-51	DIR/LVMO-98-C-002	1 & 2	N/A	SAT	SAT	SAT
6.0	AP-6.1Q	Pgs 31-39	N/A	N/A	N/A	SAT	SAT	SAT
17.0	AP-17.1Q	Pgs 117-119, 126-131	N/A	N/A	N/A	SAT	SAT	SAT
Supp I	AP-SI-1Q	Pgs 19-29	N/A	N/A	N/A	SAT	SAT	SAT
Supp III	AP-SIII.2Q	Pgs 78-92	N/A	N/A	N/A	SAT	Limited Implementation	N/I
	AP-SIII.3Q	Pgs 120-125	N/A	N/A	N/A	SAT	N/I	N/I
	QARD Subsection 2.2.1C/2.2.1C3	Pg 30	LVMO-00-D-023	N/A	N/A	SAT	UNSAT	UNSAT
Supp V	YAP-SV.1Q	Page 7	DIR/LVMO-98-D-055	N/A	N/A	SAT	UNSAT	UNSAT